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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,352	02/14/2006	Yoshiaki Sato	SUZ0027-US	3363

36183 7590 05/28/2009

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EXAMINER	
ABYANEH, SHILA	
ART UNIT	PAPER NUMBER
3764	

MAIL DATE	DELIVERY MODE
05/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,352	SATO, YOSHIAKI	
	Examiner	Art Unit	
	SHILA ABYANEH	3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,7-9,13-15 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-5, 7-9, 13-15 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The following office action is in response to the amendment filed on 07 April 2009. Claims 1-2, 4-5, 7-9, 13-15 and 19-21 are pending in the application. Claims 1-2, 4-5, 7-9, 13-15 and 19-21 are rejected as set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claims 1 (line 23), claim 4 (line 26), claim 7 (line 23), claim 8 (line 22) and claim 9 (line 25), the word "can" renders the claim indefinite because it is unclear whether the first input means is freely attached to and removed from the main body or not. Appropriate correction is required.

Claims 15 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15 and 21 are rejected because claim element "**[reading means]** and **[decision means]**" are a means (or step) plus function limitation that invokes 35 U.S.C. 112, sixth paragraph. However, the written description fails to disclose the corresponding structure, material, or acts for the claimed function. **[Specification does not specifically state what the reading means or the decision means are]**

Applicant is required to:

(a) Amend the claim so that the claim limitation will no longer be a means (or step) plus function limitation under 35 U.S.C. 112, sixth paragraph; or

(b) Amend the written description of the specification such that it expressly recites what structure, material, or acts perform the claimed function without introducing any new matter (35 U.S.C. 132(a)).

If applicant is of the opinion that the written description of the specification already implicitly or inherently discloses the corresponding structure, material, or acts so that one of ordinary skill in the art would recognize what structure, material, or acts perform the claimed function, applicant is required to clarify the record by either:

(a) Amending the written description of the specification such that it expressly recites the corresponding structure, material, or acts for performing the claimed function and clearly links or associates the structure, material, or acts to the claimed function, without introducing any new matter (35 U.S.C. 132(a)); or

(b) Stating on the record what the corresponding structure, material, or acts, which are implicitly or inherently set forth in the written description of the specification, perform the claimed function. For more information, see 37 CFR 1.75(d) and MPEP §§ 608.01(o) and 2181.

Please note that although it was stated in the previous office action that the primary reference (McEwen) did not exclusively teach the limitations that were in the previous dependent claims that are now brought into the amended independent claims, upon further consideration, the examiner realized that the primary reference (McEwen) does teach those limitations as cited below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4 and 7-9 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McEwen US Patent No. 4,469,099.

Regarding parts of the limitations of claims 1 and 7-8, McEwen teaches a muscle strength increasing system used for developing muscles of at least one of the limbs of a wearer while restricting the blood flow threrethrough by means of applying a predetermined compression pressure to the limb, the muscle strength increasing system comprising a muscle strength increasing device having a compression member/cuff (10) for tightening and compressing muscles and compression pressure controller/microprocessor for controlling the compression pressure (col. 3 lines 1-22), the compression pressure controller being for controlling the compression pressure so that it does not exceed a preset critical compression pressure (col. 3 lines 1-22), the compression pressure controller comprising: first recording means on which the preset critical compression pressure is recorded (Since the critical compression pressure is 15 mmHg more than a user selected pressure, therefore, this value (15 mmHg) has to be recorded in the microprocessor with a memory in order to perform a comparison and sound an alarm once the pressure in the cuff is more than 15 mmHg from the selected value. Therefore, it is inherent that a recording means must exist in order for the processor to know when to sound the alarm, col. 2 lines 47-57), predetermined first input means for supplying the preset critical compression pressure to the first recording means through its operation (the device has an automatic means for sensing cuff over-pressurization and triggering an appropriate alarm. once the pressure in the cuff exceeds a selected cuff pressure by more than 15 mmHg, then the alarm will sound. Therefore, the critical pressure is 15 mmHg more than a selected pressure and it is obvious that the value (15 mmHg) has been input into the system and as a result an

input means must have been involved); second recording means on which a maximum value of the compression pressure is recorded (col. 4 lines 31-54, the user is able to input a selected pressure that is within a defined range through a control panel (26). The microprocessor within the system has a memory associated with it that stores the selected value for later comparison), the compression pressure controller/microprocessor (22) controlling the compression pressure based on the maximum value of the compression pressure recorded on the second recording means (col. 4 lines 40-54), predetermined second input means/control panel (26) for supplying a maximum/user selected value of the compression pressure recorded on the second recording means (24) being controlled not to exceed the preset critical compression pressure (since the critical pressure is 15 mmHg more than the maximum/selected pressure but yet within a predetermined range, the maximum/user selected pressure will not exceed this critical pressure within the predetermined range).

Regarding claim 2, McEwen teaches a system, wherein the device comprises a hollow tight fitting band (10), having a tube (12) therein to which the air is to be supplied with a predetermined pump (14) and fastening means for use in keeping a length of the tight fitting bands in a loop having a desired size, the system comprising a pressure gauge for measuring the air pressure within the tube, the compression pressure controller being adapted to control the compression pressure based on the air pressure within the tube that is measured by the pressure gauge (col. 3 lines 1-28 and col. 4 lines 20-30).

Regarding parts of the limitations of claim 4 an 9, McEwen teaches a system that restricts the blood flow through at least one of the limbs of a wearer by means of applying a predetermined compression pressure to the limb, the muscle strength increasing system comprising a device having a compressing member/cuff (10) for tightening and compressing muscles and a compression pressure controller /microprocessor (22) for controlling the compression pressure, the compression pressure controller being configured to control the compression pressure so that the time interval during which the compression pressure is applied to the wearer falls within a range that does not exceed a preset critical compression duration (col. 2 lines 65-68, the device allows the user to select a time period within a 0-180 minute range), the compression pressure controller comprising: first recording means on which the preset critical compression duration is recorded, the compression pressure controller controlling the compression pressured based on the preset critical compression duration recorded on the fist recording means (col. 2 lines 65-68the device has an upper limit of 180 minutes as a critical duration for pressurizing the cuff. although not stated, it is implied that this upper limit is recorded within the system since the user can not increase the time beyond this limit), predetermined first input means for entering the preset critical compression duration to the first recording means through its operation (col. 2 lines 65-68, although it is not stated, the upper limit of 180 minutes has to be inputted into the system and its recording means, second recording means on which a maximum/user selected value of a time interval during which the compression pressure is applied to the wearer is recorded, the compression pressure controller controlling the

compression pressure based on the maximum/user selected value of the time interval during which the recompression pressure is applied to the wearer, which is recorded on the second recording means (col. 4 lines 31-66), predetermined second input means/control panel (26) for entering the maximum/user selected value of the time interval during which the compression pressure is applied to the wearer, to the second recording means through its operation, the maximum value being controlled not to exceed the preset critical compression duration (col. 4 lines 31-66, the user selected time period may not exceed a predetermined time value of 180 minute), and a main body having the second recording means/control panel (26) (Fig. 2).

Regarding the rest of the limitations of claim 1, 4, 7-9: wherein the first input means can freely be attached to and removed from the main body, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to manually change the critical pressure by changing the allowable difference (15 mmHg in this case) between the user selected pressure and the cuff pressure through another device such as a computer. Also since it is implied through McEwen 's invention that the critical value of pressure and time have been inputted into the system via an input means. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to separate two components (input means and controller unit) within a system, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. Nerwin v. Erlichman, 168 USPQ 177, 179.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen as applied to claim 4 above, and further in view of Burgert et al. US Patent No. 4,984,579.

McEwen teaches the invention as substantially claimed. Although McEwen teaches a timer (86) to count the time that the cuff is being pressurized, McEwen does not teach deflating or depressurizing the cuff once the selected time exceeds a predetermined time interval, but Burgert does.

Regarding Claim 5, Burgert teaches a system, wherein said compression pressure controller has time counting means for measuring time during which said compression pressure is applied, said compression pressure controller being adapted to reduce said compression pressure when the time measured by the time counting means exceeds a predetermined time interval, (col. 4 lines 21-24, wherein Burgert teaches an apparatus including a timer that once the timer runs reaches a predetermined time limit, a pressure regulator decreases the pressure that is applied by a pump).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to recognize that modifying McEwen's device with a controller that lowers the pressure in the cuff once the duration of pressurization exceeds a predetermined time as taught by Burgert would have been beneficial since a patient (user) will not be exposed to a high pressure for an extended time if the physician is not present when the timer reaches the amount of time selected. Also it is beneficial to prevent over pressurizing and damaging a muscle.

Claims 13-15 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McEwen as applied to claims 8-11 and 16-17 above, and further in view of Englehardt et al. US Patent No. 4,831,242.

McEwen teaches the invention as substantially claimed. See above. However, McEwen does not teach an authentication means, but Englehardt does.

Regarding claims 13 and 19, Englehardt teaches a compression pressure control unit, comprising authentication means for determining whether or not an input from said first input means is allowed, wherein the input from said first input means is accepted only when said authentication means performs authentication indicating that the input is permitted, (col. 2 lines 18-24, the control system with an input device includes a card reader for reading a membership card to authenticate a user).

Regarding claims 14 and 20, Englehardt teaches a compression pressure control unit, wherein said authentication means comprises: an authentication operator for entering data for authentication; and decision means for determining whether the data for authentication received from the authentication operator are valid, said authentication being made when said authentication means determines that said data for authentication are valid, (col. 2 lines 18-24, col. 3 lines 12-14, col. 6 lines 40-63 and col. 7 lines 20-32, the control system with an input device includes a card reader that identifies a user based on the information on their card. Although it is not exclusively stated, it is implied that a decision means must exist in order to authorize a user based on the information provided on the card).

Regarding claims 15 and 21, Englehardt teaches a compression pressure control unit, wherein said authentication means comprises: reading means for reading data for authentication from a predetermined recording medium; and
decision means for determining whether said data for authentication read by the reading means are valid; said authentication being made when said authentication means determines that said data for authentication are valid, (col. 2 lines 18-24, col. 3 lines 12-14, col. 6 lines 40-63 and col. 7 lines 20-32, the control system has an input device with a card reader that identifies a user based on the information on their card. Although it is not exclusively stated, it is implied that a decision means must exist in order to authorize a user based on the information provided on the card).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to recognize that modifying McEwen's device with an authentication means as taught by Englehardt would have been beneficial to allow a user who is authorized to change and store various information in their profile and exercise accordingly. The combination will prevent others to change or store any information that is not relevant to the user or is dangerous for the user.

Response to Arguments

Applicant's arguments filed on 21 April 2009 have been fully considered but they are not persuasive. The applicant's argument on pg. 14 that the examiner has presented two distinct obviousness rational for claims 12 and 18, the examiner would like to point out that the layout of the office action has caused this misinterpretation. The second paragraph on pg. 16 of the previous office action uses a case law in order to provide an obvious rational in rejecting the limitations of claims 12 and 18. However, the third paragraph on pg. 16, is the obvious rational for combining the three references used (Lampropoulos, McEwen and Ono's) for rejecting claims 11 and 17 and is **NOT** used as a rational for rejecting claims 12 and 18.

In regards to applicant's argument on pages 14-15 that the input means of McEwen's device is not separable from the main body, the examiner respectfully disagrees. as it was mentioned in the office action, the first input means is used to input a critical compression pressure value into the first recording means and since this critical compression pressure value is 15 mmHg above the user selected value, it is obvious that this value has been input/programmed into the device via another device such as a computer at the time of manufacturing by the manufacturer and therefore it serves as a separate input means from the second input means which is the control panel. Also it would have been obvious to one having ordinary skill in the art at the time the invention was made to have two input means for the critical and maximum pressure, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177,179.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHILA ABYANEH whose telephone number is (571)270-7403. The examiner can normally be reached on 7:30 am- 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn H. Thanh can be reached on (571)272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. A./
Examiner, Art Unit 3764
05/21/2009

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764